

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 4, 2010 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1, 3, 6, 7, 9, 12, 13, 16-18, 21-24, 27-29, 31, 55, 57-60, 62, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al.

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(5,562,685) in view of Beyer et al. (4,563,961) and Zocher (3,469,548), and further in view of Yoon (5,437,680). Mollenauer et al. disclose the invention substantially as claimed. Mollenauer et al. disclose, at least in figures 1 and 12 and in col. 9, line 37 to col. 10, line 5; a suturing device including a handle (102 or 12) extending along axial direction, an elongated shaft (104, with respect to claims 1, 3, 6, 7, 9, 12, 13, 16-18, 21-24, 27-29, 31, 55, 57-60, and 62) with a distal end and extending along an axial direction, a sharpened tip (106 or distal portion of 104) attached to (i.e. joined to) a distal end of the elongated shaft, and a detachable suture (110) that is a length of material; where the sharpened tip (106 and distal portion of 104) includes an elongated opening (108) configured to trap a suture at a selected point and including a curved portion and configured to permit suture to pass lengthwise through the opening, where the sharpened tip (106 and distal portion of 104) has a hooked configuration or is angularly bent relative to the shaft in a selected direction, where the sharpened tip is curved at least partially about the distal end of the shaft (proximal portion of 104 connected to 102) or extends at an angle and to one side of the distal end, where the sharpened tip (distal portion of 104) extends at least partially forward from the distal end with a concave configuration, where the sharpened tip is angularly bent about a tip axis that is non-parallel with the axial direction (i.e., each coil portion of the needle, including the tip, is angled with respect to the axial direction) and is curved about the axial direction; and where the handle is located in-line with the shaft (i.e., the longitudinal axis of the handle is in-line with the central axis of the "coiled projection" that is shaft 104).

However, Mollenauer et al. do not disclose a sharpened tip including an exposed, tapered, and closed opening or an opening with at least a portion dimensioned to wedge and hold a suture, having a central portion with a tapered configuration, or comprising a tapered opening, where the sharpened tip includes at least one flat surface. Beyer et al. teach, at least in figures 2 and 3 and in col. 2, line 61 to col. 3, line 9; a device with a sharpened tip including an opening (7) that is exposed, tapered, and closed; or has at least a portion dimensioned to wedge and hold a suture, or is tapered from a distal closed edge to a proximal closed edge (at 20). The opening is positioned within a flat surface (14) of the sharpened tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the opening of the device of Mollenauer et al., so that it has the tapered configuration as taught by Beyer et al. Such an opening would enhance the trapping of a suture at a selected point, so that a user can manipulate the suture and sharpened tip with better control during suturing (i.e., the suture would less likely move inadvertently in an opening as taught by Beyer et al.). Moreover, modifying the sharp tip of the device, so that it has at least one flat surface would allow the device to have a small cross-sectional profile for penetration of tissue while carrying a suture through the penetration.

However, Mollenauer et al. in view of Beyer et al. do not disclose that the opening is continuously tapered as claimed. Zocher teaches, at least in figure 8 and in col. 3, lines 42-52, a needle with an eye that is continuously tapered (“substantially conical”), and like Beyer et al., the eye is offset from the longitudinal axis of the needle. It would have been obvious to one having ordinary skill in the art at the time the

invention was made, in view of Zocher, to modify the eye of Mollenauer et al. in view of Beyer et al., so that is continuously tapered as claimed. Such an eye configuration would allow focused direction of a suture to the narrow portion of the eye, where improved support for the suture is provided during movement of the needle and suture.

Finally, Mollenauer et al. in view of Beyer et al. and Zocher disclose the invention substantially as claimed, but do not disclose that the sharpened tip with an opening or the needle with a through opening is separately attached to or detachable from the distal end of the elongated shaft, where the elongated shaft is separately attached to or detachable from a handle, and where (with respect to claim 63) the elongated shaft has a straight configuration (and element 104 of Mollenauer et al. is deemed the sharpened tip with respect to claim 63), or where the suturing device comprises three separate pieces (handle, elongated shaft, and sharpened tip). Yoon teaches, at least in figures 16 and 17 and in col. 9, line 65 to col. 10, line 7; a three-piece device with a handle (112) separately attached to an elongated shaft (104) with a straight configuration and including a detachable or separable needle (94) at the distal end of the shaft and holding a suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Yoon, to modify the device of Mollenauer et al. in view of Beyer et al. and Zocher, so that the sharpened tip with an opening or the needle with a through opening is detachable from the distal end of the elongated shaft, where elongated shaft has a straight configuration. A needle with a suture detached from the elongated shaft would allow a surgeon to manipulate the needle itself for stitching of tissue without any physical interference from the elongated shaft. Also, the

elongated shaft would be capable of receiving new or replacement needles, while an elongated shaft with a straight configuration would allow insertion of the device into a patient's body through a narrow opening for a minimally-invasive surgical procedure. Additionally, it would be obvious to one having ordinary skill in the art at the time the invention was made, to include a handle that is separately attached or detachable from the elongated shaft of Mollenauer et al. in view of Beyer et al. and Zocher. Such a configuration would allow disassembly of components of the device for cleaning, sterilization, and/or replacement of the components.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. (5,562,685) in view of Orthwine (2,416,117) and Leighton (1,055,058), and further in view of Yoon (5,437,680). Mollenauer et al. disclose the invention substantially as claimed. Mollenauer et al. disclose, at least in figures 1 and 12 and in col. 9, line 37 to col. 10, line 5; a suturing device including a handle (102 or 12) extending along axial direction, an elongated shaft (104) with a distal end and extending along an axial direction, a sharpened tip (106 or 104) attached to (i.e., joined to) a distal end of the elongated shaft, where the sharpened tip (106) includes an exposed and closed opening (108) configured to trap a suture at a selected point. However, Mollenauer et al. do not disclose that the opening includes a tapered configuration with central axial region that is narrower than proximal and distal regions along a direction perpendicular to the axial direction to trap a suture at a selected point within the opening and to permit the suture to pass lengthwise through the opening. Orthwine teaches in the figures and in col. 1, lines 12-29, a needle opening including a tapered configuration

having central axial region ("restriction") that is narrower than proximal and distal regions (6, 7) along a direction perpendicular to the axial direction to trap a suture at a selected point within the opening and to permit the suture to pass lengthwise through the opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Orthwine, to modify the opening in the device of Mollenauer et al., so that the opening is configured as claimed. Such an opening would ease threading of the needle and allow a suture or thread to be retained by the needle.

However, Mollenauer et al. in view of Orthwine do not specifically disclose that the central axial region is open, although it does open upon passage of a suture through the region. Leighton teaches in figures 1-3 and lines 93-98; an opening in a needle that includes an open central region (5). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Leighton, to modify the central axial region of the opening in the needle of Mollenauer et al. in view of Orthwine. Such a modification would ease passage of the suture along the opening between the proximal and distal regions.

Finally, Mollenauer et al. in view of Orthwine and Leighton disclose the invention substantially as claimed, but do not disclose that the sharpened tip with an opening or the needle with a through opening is separately attached to or detachable from the distal end of the elongated shaft, where the elongated shaft is separately attached to or detachable from a handle. Yoon teaches, at least in figures 16 and 17 and in col. 9, line 65 to col. 10, line 7; a device with a handle (112) separately attached to an elongated shaft (104) including a detachable or separable needle (94) at the distal end of the shaft

and holding a suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Yoon, to modify the device of Mollenauer et al. in view of Orthwine and Leighton, so that the sharpened tip with an opening or the needle with a through opening is detachable from the distal end of the elongated shaft. A needle with a suture detached from the elongated shaft would allow a surgeon to manipulate the needle itself for stitching of tissue without any physical interference from the elongated shaft. Also, the elongated shaft would be capable of receiving new or replacement needles. Additionally, it would be obvious to one having ordinary skill in the art at the time the invention was made, to include a handle that is separately attached to or detachable from the elongated shaft of Mollenauer et al. in view of Orthwine and Leighton. Such a configuration would allow disassembly of components of the device for cleaning, sterilization, and/or replacement of the components.

***Response to Amendment***

5. Applicant's arguments with respect to rejections based on Mollenauer, Beyer, Zocher, Yoon, or any combination of these references have been considered but are not persuasive. That is, the Examiner did not base the rejections on an "obvious-to-try rationale" with the references, as the Applicant argued. The Examiner based the reconstruction of the Applicant's invention on knowledge from the references, which was within the level of ordinary skill in the art and within the same or analogous art. Yoon, for instance and as mentioned in the above rejection, also teaches an elongated shaft with a straight configuration, where the elongated shaft is separate from a handle and a sharpened tip.

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773